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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,274	09/24/2003	Andy Wolff	26486	3490

67801 7590 12/10/2008

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EXAMINER	
MACNEILL, ELIZABETH	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,274	WOLFF ET AL.	
	Examiner	Art Unit	
	ELIZABETH R. MACNEILL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20,25-45,47,52-54 and 118-121* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20,25-45,47,52-54 and 118-121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 October 2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-18, 20, 25-45, 47, 52-54 and 118-121are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not teach drug release to “an outer surface of the oral mucosa” to one of ordinary skill in the art. There is no illustration or description of the oral mucosa, let alone an outer surface of the oral mucosa.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-4, 11-16,18,20,25-31,38-43,45,47,52-54, and 118-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakuma et al (US 5,584,688) in view of Pfeiler et al (US 5,558,640)

Sakuma et al teaches an oral device for controlled drug release comprising a reservoir (3) containing a drug configured for release into an outer surface of an oral mucosa (the gingiva) via passageway (4) and an oral anchoring element (1/2). The top passageway 4 in Fig 1 delivers drugs to the outer/edge surface of the gingiva. The device is a dental bridge. See also removable cap (3, Fig 10). See upper portion which is hard and is a biting surface.

Sakuma does not teach an electronic drug release mechanism, but does teach a "micropump" (13, Fig 11).

Pfeiler teaches an implantable element with electronic drug release mechanism (10) As to claim 2,3,18,29,30,45 see control unit processor, release mechanism and power source within (10), Col 3 at line 35); claim 4,31 see processor/memory (4) which includes "schedules," considered to be a calendar; claim 11-14,38-41 telemetry units (8,12,16); claim 15,16, 42,43sensor unit (9). As to claims 118-119, the base 1 has multiple perforations 4. As to claims 120-121,

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the electronic pump and external sensor of Pfeiler with the oral delivery device of Sakuma to provide a means to controllably release a drug into the oral mucosa.

3. Claims 1-4, 11-16,18,20,25-31,38-43,45,47, 52-54 and 120-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cournet et al (US 4,020,558) in view of Pfeiler et al (US 5,558,640)

Cournet et al teaches an oral device for controlled drug release comprising a reservoir (2) containing a drug configured for release into an outer surface of an oral mucosa (the gingiva) and an oral anchoring element (4, 46). The drug comes in contact with the outer surface of the oral mucosa via dissolution in the saliva. See also molar band 46 and 56, Fig 10. Cournet does not teach an electronic drug release mechanism. Instead, Cournet relies on the solubility of the release compound of the drug

Pfeiler teaches an implantable element with electronic drug release mechanism (10)

As to claim 2,3,18,29,30,45 see control unit processor, release mechanism and power source within (10), Col 3 at line 35); claim 4,31 see processor/memory (4) which includes "schedules," considered to be a calendar; claim 11-14,38-41 telemetry units (8,12,16); claim 15,16, 42,43sensor unit (9)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the electronic pump and external sensor of Pfeiler with the oral delivery device of Cournet to provide a means to controllably release a drug into the oral

mucosa. Pfieler allows the user to adjust the drug delivery rate, including allowing bolus doses and doses which respond to a sensed body condition.

4. Claims 5-10 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakuma/Pfeiler as applied above, and further in view of Feingold (US 4,871,351)

Sakuma/Pfeiler does not teach two local sensors. Feingold teaches an implantable drug delivery device with local sensors. Local sensor (23) indicates a low battery; sensor 30 measures glucose in the surrounding fluids. The use of sensors to monitor pump conditions such as low battery, refill detection, occlusion detections, and short circuits are well known in the pump art for safety purposes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use sensors of Feingold in order to monitor the pump conditions and prevent failure of the device and glucose levels to protect the patient from an overdose or pump malfunction

5. Claims 5-10 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cournet /Pfeiler as applied above, and further in view of Feingold (US 4,871,351)

Cournet /Pfeiler does not teach two local sensors. Feingold teaches an implantable drug delivery device with local sensors. Local sensor (23) indicates a low battery; sensor 30 measures glucose in the surrounding fluids. The use of sensors to monitor pump conditions such as low battery, refill detection, occlusion detections, and short circuits are well known in the pump art for safety purposes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use sensors of Feingold in order to monitor the pump conditions and prevent failure of the device and glucose levels to protect the patient from an overdose or pump malfunction

6. Claims 17 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakuma/Pfeiler as applied above, and further in view of Eppstein et al (US 5,458,140)

Sakuma/Pfeiler does not teach an iontophoresis device. Eppstein teaches a sonophoresis device for drug delivery.

It would have been obvious to one ordinary skill in the art at the time the invention was made to use the sonophoresis in order to improve delivery of the drug through the patient's oral tissue.

7. Claims 17 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cournet /Pfeiler as applied above, and further in view of Eppstein et al (US 5,458,140)

Cournet /Pfeiler does not teach a sonophoresis device. Eppstein teaches a sonophoresis device for drug delivery.

It would have been obvious to one ordinary skill in the art at the time the invention was made to use the sonophoresis in order to improve delivery of the drug through the patient's oral tissue.

Response to Arguments

8. Applicant's arguments have been considered but are not persuasive. Applicant argues that the rejections do not teach delivery to the outer surface of the oral mucosa. First, the examiner believes this limitation to be new matter. Sakuma clearly teaches delivery to the outer edge of the gingiva, which is an oral mucosal membrane. The limitation "into the gingiva" indicates that Sakuma's device is not limited to injection "under" the gingiva. Cournet teaches delivery to the saliva which transports medicine to the outer surface of the oral mucosa. As to applicant's argument that Cournet does not teach a molar band, see Fig 10.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767